

# HOGAN & HARTSON

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March 11, 2004

*BY HAND DELIVERY*

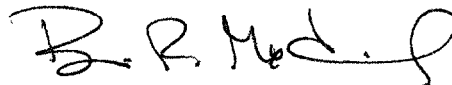
Dockets Management Branch, HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Re: Submission to Docket No. 03P-0126**

Dear Sir or Madam:

Please include the following letter in Docket No. 03P-0126.

Sincerely,



Brian R. McCormick  
Hogan & Hartson L.L.P.

Enclosure

03P-0126

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Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Re: Docket No. 03P-0387/CP1  
Notice of Intent to Respond to Comments**

Dear Sir or Madam:

On March 2, 2004, we obtained from the Food and Drug Administration a copy of comments submitted by Hyman, Phelps & McNamara, P.C. in opposition to the above-referenced Citizen Petition (the "Petition"). The comments raise substantive and technical issues that bear directly on the Petition.

By this letter, we are providing notice of our intent to respond to the comments on behalf of the petitioner, Abbott Laboratories, on or before April 15, 2004. We also intend to include with our response a copy of a peer-reviewed article on Abbott's Study M02-417, to be published later this month in the journal *Thyroid*. Study M02-417 is a central piece of evidence in support of the Petition.

As discussed in FDA's May 15, 2003, letter from Jane Axelrad to Douglas Sporn, the agency invited Abbott to initiate this Citizen Petition process in order to, among other things, "provide Abbott the opportunity to comment publicly on the views and opinions of others . . . ." We welcome this opportunity and, as noted above, will submit our response to Hyman, Phelps on or before April 15, 2004.

HOGAN & HARTSON L.L.P.

Dockets Management Branch

March 11, 2004

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As always, we appreciate your time and courtesy in this matter.

Sincerely,

DM Fox /BMC

David M. Fox  
Brian R. McCormick  
Hogan & Hartson L.L.P.

cc: John M. Leonard, M.D.  
Douglas L. Sporn  
Neal B. Parker  
Abbott Laboratories

Kevin M. Fain  
Office of the Chief Counsel, GCF-1

FDA Docket No. 03P-0126